VENABLE LLP

Venable Vitae

A PUBLICATION OF VENABLE'S LIFE SCIENCES GROUP

www.Venable.com
January 2010

One of the nation's leading law firms, Venable provides comprehensive legal services in representing fast-growing and emerging life science companies—including advice on corporate affairs, protection of intellectual property, help in dealing with the government and strategies for resolving disputes.

Our Life Sciences attorneys, including many with advanced degrees in scientific fields, offer a combination of technical expertise and business and legal experience to complete projects done quickly in today's competitive environment.

Venable lawyers practice in all relevant legal specialties:

- Corporate Formation and Finance
- IP - Patents and Trademarks
- Technology Transactions
- Regulatory
- Government Contracting
- Government Relations
- Tax Issues
- Real Estate
- Labor and Employment
- International Trade
- Product Liability
- Patent Litigation

For more information about Venable's Life Sciences team, visit www.venable.com/life-sciences.

Venable Vitae provides a convenient compilation of articles and listing of events relevant to Life Sciences companies - whether just starting up or established, nonprofit or for profit. This industry faces an increasingly complex set of challenges ranging from technology and science to business, policy and legal matters. We hope this publication helps shed some light on these topics.

In This Issue:

Hot Topic

The New Normal

As the second new year of the Great Recession begins, it seems that uncertainty has become the new normal. Transformation is inevitable, but to what? The pace of change is so swift that precedent offers little guidance. Our clients have responded in different ways, some investing in completely new endeavors, others just trying to maintain their market position. Some rely on strategic plans.

In a nutshell, strategic planning involves six steps: (1) identify one or more organizational goals, (2) study the competitive environment, (3) assess internal resources, (4) define a simple long-term plan, (5) take action to put the plan into effect, and (6) reassess as necessary. Each step is crucial, and requires coordinated effort by business, technical, and legal experts, based on objective information. Uncertain times may call for more frequent reassessment of a strategic plan. Although we can't predict the future, we must continue to plan for it, nonetheless. When it comes to the need for planning, the more things change, the more they remain the same.

Survey

We would appreciate your input about legal seminars for life sciences companies that we are developing for 2010. Please take a moment to complete this one page survey. Click here to access the survey.

Articles

Click on any headline for more information or to view the article in its entirety.

DOJ Targets Pharmaceutical and Life Sciences Companies for FCPA Enforcement

The U.S. Department of Justice ("DOJ") has spoken, and U.S. pharmaceutical and life sciences industries should listen. DOJ has set its sights on "the application of the Foreign Corrupt Practices Act ("FCPA") to the pharmaceutical industry in the months and years ahead," said Lanny A. Breuer, Assistant Attorney General for DOJ's Criminal Division. In his November 2009 address to the "Pharmaceutical Regulatory and Compliance Congress and Best Practice Forum," Breuer made clear that DOJ will focus on the pharmaceutical and life sciences industries, where non-U.S. sales are "close to $100 billion dollars, or roughly one-third," of the total industry revenue.

New Executive Order Makes Green Initiatives a Priority for Federal Agencies

On December 28, 2007, the Office of Federal Procurement Policy proposed issuing a policy letter, "Acquisition of Green Products and Services Policy," providing guidance on green purchasing policies and strategies for the federal government. The policy would have directed agencies to identify opportunities and to give preference to the acquisition of green products and services, including: alternative fuels and alternative fuel vehicles and hybrids, bio-based products, Energy Star and Federal Energy Management Program-designated products, environmentally-preferable products and services, electronics registered on the Electronic Product Environmental Assessment Tool, low or no toxic or hazardous chemicals or materials or products, non-ozone depleting substances, recycled-content and/or remanufactured products, renewable energy, and water-efficient products.

DOE Announces Additional Funding for Transformational Energy Research Projects

On Monday December 7, 2009, the Department of Energy ("DOE") announced a second round of funding through the DOE's Advanced Research Projects Agency-Energy ("ARPA-E") for innovative and cutting-edge clean energy projects. This latest round of funding, in which up to $100 million is available, is focused on spurring development in three specific technology areas: electrofuels, carbon capture technologies, and batteries for electrified transportation. The latest solicitations from ARPA-E seek to promote research and development in three key areas, one of which is electrofuels. While significant research and development has been devoted to biofuels, this solicitation seeks to pursue new approaches to efficiently convert carbon dioxide and electrical energy to infrastructure-compatible liquid fuels. Specifically, research will focus on the use of organisms and biological systems or other innovative processes.

DOE Rule Change To Loan Guarantee Program

The DOE may now guarantee loans to innovative energy projects with multiple investors, differing ownership interests, or financing from other lenders. On Monday, December 7, the Department of Energy ("DOE") announced an important change to the structure of its Loan Guarantee Program, under which the Federal Government will guarantee loans to companies deploying new or significantly improved technologies that reduce air pollutants and greenhouse gas emissions. The loan guarantees are available to any company looking to employ energy technologies related to: biomass, hydrogen, solar, wind, hydropower, clean coal, carbon sequestration, electricity transmission, alternative fuel vehicles, energy efficiency projects, and pollution control.

SEC Adopts Executive Compensation and Corporate Governance Disclosure Enhancements

On December 17, 2009, the SEC adopted new executive compensation and corporate governance disclosure requirements that will become effective February 28, 2010. These final rules reflect final action taken on certain of the SEC's July proposals we wrote about last summer. Importantly, however, the SEC has deferred action on the proxy access proposal and proposed amendments to the proxy solicitation procedures.

December "Payroll Surprise" Waiting for Some Employers in 2010

Employers paying their salaried exempt workers on a bi-weekly basis – and for whom January 1, 2010 was a pay date – may be surprised to learn that, due to a quirk of the Gregorian calendar, there are 27 pay dates in the year 2010, rather than the typical 26.

Federal COBRA Subsidy Expanded

Tucked at the end of the Department of Defense Appropriations Act, 2010 (“DOD Act”), which was signed into law by President Obama on December 19, 2009, are provisions substantially expanding the Federal COBRA subsidy enacted as part of the American Recovery and Reinvestment Act of 2009 (“ARRA”). As originally enacted under ARRA, the Federal COBRA subsidy allows certain eligible individuals who experience an involuntary termination and lose health coverage between September 1, 2008 and December 31, 2009, to continue coverage pursuant to COBRA for up to nine months at 35% of the premium.

Events

European Pharmaceutical Regulatory Law Boot Camp

Venable FDA attorney Jill Deal and Alison Dennis of our strategic partner firm Field Fisher Waterhouse will be speaking at this conference on how to navigate the European regulatory maze that plays such an essential part in the successful commercialization of pharmaceutical and biological products.

January 25, 2010 and January 26, 2010
The Carlton on Madison
New York, NY

Spotlight

Foreign Corrupt Practices Act (FCPA)

Vigorous enforcement of the Foreign Corrupt Practices Act (FCPA) has become a top priority for both the Department of Justice (DOJ) and the Securities and Exchange Commission (SEC). Recently, both have increased resources dedicated to FCPA enforcement, with a special focus on the pharmaceutical industry. At the same time, civil and criminal penalties for FCPA violations continue to grow and the DOJ has shown an increasing willingness to criminally prosecute individuals for FCPA violations. In addition, many other nations have enacted and/or have begun to seriously enforce anti-corruption legislation of their own. As such, any business operating in the global marketplace must make the FCPA and anti-corruption an integral part of its business plan.

Firm in the belief that the best legal counsel prevents problems rather than reacts to them, we apply our regulatory know-how and years of experience to design FCPA/anti-corruption compliance programs for companies in the United States and abroad.

Preventing violations
With the nuances of each client’s business in mind, we:

- **create policies and procedures** that address not only the FCPA, but the other major international anti-corruption initiatives, as well;
- **train employees and agents** in the FCPA and other anti-corruption legislation;
- **analyze form documents** such as purchase orders and distributorship agreements to decrease the company’s FCPA/anti-corruption exposure; and
- **design effective protocols** to monitor FCPA/anti-corruption compliance.

Conducting internal investigations
Venable attorneys have broad experience conducting FCPA and other international internal investigations. We gather the facts wherever they may be and analyze them with the perspective that comes from having dozens of years of DOJ and SEC experience. Our intimate knowledge of how these agencies conduct investigations enables clients to make sound business judgments in an often fast-moving environment.

Defending your company and your people
Our FCPA team brings dozens of years of experience defending corporations and individuals in SEC and federal criminal investigations involving the FCPA and other complex regulatory matters. Our attorneys know well the inner workings of the SEC and DOJ and combine this knowledge with vigorous investigation and advocacy to attempt to prevent charges or negotiate a favorable disposition. Should that not be possible, our FCPA team includes savvy and experienced trial lawyers with hundreds of federal jury trials to their credit.

For more information, please visit http://www.venable.com/foreign-corrupt-practices-act-and-anti-corruption-practices/.

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